

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/420,719	10/20/99	MIYASHITA	M 10059-308 (P2)

000570 HM12/0320
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EXAMINER
PADMANABHAN, K

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 03/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/420,719	MIYASHITA ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 February 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s). _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a sample supply unit made of sponge, does not reasonably provide enablement for a sample supply unit made of all elastic materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has only used a sample supply unit made of sponge for retaining the sample, and has not provided sufficient guidance or working examples to enable one to practice the invention with other elastic material. Due to the lack of predictability of the claimed invention without this guidance, undue experimentation would be required of one of skill in the art to make and use the invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5, 7, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "proper" in claims 5 and 7 is a relative term which renders the claim indefinite. The term "proper" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 2-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al. (US Pat. 5,262,305). Heller et al. disclose a biosensor including an interferant eliminating catalyst. The apparatus of the invention has an interferant eliminating layer, including a catalyst, wherein the catalyst is capable of oxidizing and thereby eliminating a plurality of interfering compounds from the sample before it reaches the sensor (col. 1). The catalyst mediates oxidation of an interferant in the presence of an oxidant to yield a non-interfering compound that does not interfere with the biosensor's function. In addition, the catalyst may be a natural enzyme (col. 4). Furthermore, the apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are also located on either sides of the control means, as a sample enters the top of the layer, travels through the layer, where interferants are removed, and

then is released to the sensing layer from the bottom of the interferant removing layer (figures 2 and 3).

9. Claims 2-3, 5, and 7-9 rejected under 35 U.S.C. 102(b) as being anticipated by Foulds et al. (US Pat. 5,124,253). Foulds et al. disclose a device and method, wherein isozymes are employed to remove or inactivate endogenous alkaline phosphatase, thereby minimizing interference. In addition, the system also comprises a suitable buffer to alter the pH of the sample solution, often blood with a pH of 7.4, to an alkaline value suited to the enzyme of the test element (col. 4). The apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are located on either sides of the control means, as a sample enters one side of the layer, travels through the layer, where interferants are removed, and then is released on the other side.

10. Claims 2-3 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al. (US Pat. 4,431,507). Nankai et al. disclose a device in which an electrode is provided to electrochemically oxidize interfering materials in the sample solution. The enzyme of the electrode oxidizes interfering materials such as uric or ascorbic acid (col. 3). The apparatus of the reference inherently includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample.

11. Claims 4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bockowski (US Pat. 5,271,819). Bockowski et al. disclose a sensor electrode and a method for detecting selected characteristics in a sample solution. The reference discloses the use of absorbents, such as activated carbon, to remove specific contaminants or interferants from the sample solution (col.

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3). The solution is then allowed to reach the biosensor. The apparatus of the reference includes a sample introducing part and sample releasing part, as these parts are interpreted as any part of the apparatus that allows the entry and release of a sample. These parts are also located on either sides of the control means, as a sample enters on one side of the adsorbent, travels through the adsorbent where interferants are removed, and then is released to the sample region on the other side of the adsorbent.

12. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Barden (US Pat. 4,279,618). Barden discloses a method and apparatus for determining the level of sulfuric acid in atmospheric air which also contains interferants. The method comprises the removal of interferants before the measurement of sulfuric acid content. The apparatus includes a sample introducing part, a control means for removing the interferants, and a sample releasing part, wherein sulfuric acid content is measured after the interferants have been removed from the sample and it is released to the rest of the apparatus. The apparatus also comprises heating means of the sample.

Response to Arguments

13. Applicant's arguments and amendments filed February 5, 2001 have been fully considered and are sufficient to overcome the 102 (b) rejections over Yoshioka et al. (US Pat. 5,229,282), Yoshioka et al. (US Pat. 5192,415), and Amano et al. (US Pat. 5,385,830) cited in the previous office action. However, applicant arguments concerning the 102 (b) rejections over Heller et al. (US Pat. 5,262,305), Foulds et al. (US Pat. 5,124,253), Nankai et al. (US Pat. 4,431,507), and Bockowski et al. (US Pat. 5,271,819) are unconvincing and these rejections have been maintained.

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14. Applicant's assertion that the term "proper" in claims 5 and 7 is definite is not convincing. If applicant intends this term to mean that the sample will be adjusted to have a pH range for the optimal functioning of the enzyme for use with the invention or the sample will have all interfering substances eliminated from the sample, these limitations should be recited in the claims.

15. Applicant's argument that none of the references teach a control means for placing a sample in condition for analysis with a biosensor is not convincing. The above cited references, namely Heller et al., Foulds et al., Nankai et al., Bockowski et al., and Barden, all teach control means. As described in the specification and in applicant's arguments, control means simply refers to catalysts, adsorbents, or buffers that convert interfering substances into "harmless" substances or remove them all together. As discussed above, the cited references possess control means according to this interpretation.

16. Applicant's arguments that the cited prior art have interfering reducing means that are physically or chemically coupled with the detection portion of the biosensor is moot, as the claims do not have a limitation wherein the interferant elimination portion of the apparatus must be separate in any way from the biosensor.

Conclusion

Claims 2-10 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4243 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

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March 12, 2001


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641